INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY
UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Scott Cordray	Atty. Dkt. No.: COR170-10/99121 PCT
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Title:	NASAL SPRAY HAVING DEAD SEA SALT	

Box PCT
Director for Patents & Trademarks
Washington, D.C. 20231

STATEMENT UNDER ARTICLE 34(b)

This is in response to the First Written Opinion of the International Preliminary Examination Authority mailed June 15, 2001.

Claims 1 and 2 were thought to lack novelty over Japanese Abstract 60164467, indeed this abstract concerns processed Dead Sea salts as nutritious post exercise beverage. Claims 1 and 2 of the present invention concern "a nasal spray formulation" not a beverage. Should anyone make a Dead Sea salt beverage it would appear not to be infringing claims 1 and 2 unless perhaps there was s cific advice on the beverage container to spray the beverage in one's nose.

Claims 7 d 8 were thought to lack novelty over EP 0937453 A2. Again, this reference envisions Dead Sea salt aqueous solution for an entirely different purpose. In this case the primary purpose is the cleansing of skin and of teeth. Applicant does not deny that Dead Sea salts, which have been available for thousands of years, have been previously dissolved in water and used for various purposes. However, none before the present inventor had ever discovered that a Dead Sea salt formulation is an effective nasal spray. Although EP 0937453 A2 mentions on page 8 that "a different composition of the formula can be used for inhaling to ease nasal or

sinus congestion and to soothe coughing irritations due to bronchitis or similar conditions", no guidance is given as to the nature of this "different composition of the formula." It is also noted that this is just one of many different possible uses speculated upon by this reference. The primary uses taught are cosmetic and tissue cleansing. Of course, this reference has no clinical showing of any effectiveness for nasal congestion. The present application has such clinical evidence and indeed has a specific recommended composition for such internasal usage. Thus, it is believed that EP 0937453 A2 neither teaches or renders obvious the present invention. One of skill in the art studying this European patent application would not conclude that this minor proposed usage is in fact of significance because there is no showing of evidence therefor. It is among one of many proposed uses, and a minor one at that.

Although EP 0937453A2 states that sinus or nasal problem may be eased by inhaling a different composition of the described formula, no different formulation is described and no experimental proofs are offered. Applicant proposes that this is the merest wild speculation.

Applicant requests deletion of original pages 4-5 and 8-13 and their replacement by the appended substitute pages 4-5 and 8-13. The replacement specification pages and claim pages are to correct the typographical error in the placement of a decimal point. The Example mentions a specific formulation of 12 g of Dead Sea salts per 480 ml (which is 25g/liter). The wt/wt percentage is inherent in the exemplary material.

Applicant respectfully requests a positive preliminary examination report.

Respectfully submitted,

Daniel S. Hodgins, Reg. No. 31,026
JACKSON WALKER LLP
112 E. Pecan St., Ste 2100
San Antonio, TX 78205
(210)978-7700 tel (210)978-7790 fax

Attorney for Applicant

SUBSTITUTE 8

CLAIMS:

1. A nasal spray formulation comprising:

a Dead Sea salt and mineral composition in aqueous solution.

2. The formulation of claim 1 where the aqueous solution is sterile.

3. The formulation of claim 1 defined further as containing a buffer.

4. The formulation of claim 3 where the buffer is to maintain a pH of from about 6.5 to about 7.5.

5. The formulation of claim 1 where the composition is from about 5.0 to about 50.0 grams per liter of aqueous solution.

6. The formulation of claim 1 where the composition is about 25.0 grams per liter of aqueous solution.

7. The formulation of claim 1 where the composition is essentially free of noxious organic impurities.

8. The formulation of claim 1 wherein said Dead Sea salt and mineral composition is further defined as including about 31-35% (wt/wt) magnesium halide, about 24-26% (wt/wt) potassium halide, about 4-8% (wt/wt) sodium halide, about 0.4-0.6% (wt/wt) calcium halide, the halide being about 0.3 -0.6% (wt/wt) bromide and about 99.4-99.7% (wt/wt) chloride.

9. A method of treating symptoms of adverse conditions affecting the nasal cavity and passageway, the method comprising the steps of identifying patient with an adverse nasal cavity conditions;

a. obtaining a premixed formulation containing a Dead Sea salt and mineral composition in aqueous solution; and

b. administering an aerosol formed from the formulation at least 1 time a day as symptoms of the patient persist.

10. The method of claim 9 wherein said conditions include rhinitis, sinusitis, epistaxis and post-surgical irritation.

11. The method of claim 9 wherein said Dead Sea salt and mineral composition is in sterile aqueous solution.

12. The method of claim 9 wherein said Dead Sea salt and mineral composition in aqueous solution contains a buffer.

13. The method of claim 12 wherein the buffer is to maintain a pH from about 6.5 to about 7.5.

14. The method of claim 9 wherein said Dead Sea salt and mineral composition in aqueous solution is from about 5.0 to about 50.0 grams of salt per liter of said aqueous solution.

15. The method of claim 9 wherein said Dead Sea salt and mineral composition in aqueous solution is about 12.0 grams of salt per 480 cc of said aqueous solution.

16. The method of claim 9 wherein said Dead Sea salt and mineral composition is further defined as including about 31-35% (wt/wt) magnesium halide, about 24-26% (wt/wt) potassium halide, about 4-8% (wt/wt) sodium halide, about 0.4-0.6% (wt/wt) calcium halide, the halide being about 0.3 -0.6% (wt/wt) bromide and about 99.4-99.7% (wt/wt) chloride.

17. The method of claim 9 wherein said Dead Sea salt and mineral composition in aqueous solution is essentially free of organic impurities.

18. A method for treating symptoms of adverse conditions of the nasal cavity and passageway with a Dead Sea salt and mineral composition in aqueous solution, the method comprising the steps of obtaining a premixed formulation containing a Dead Sea salt mineral composition in aqueous solution; and self administering an aerosol formed from said formulations nasally at least 1 time a day as symptoms persist.

19. The method for claim 18 wherein said conditions include rhinitis, sinusitis, epistaxis and post-surgical irritation.

20. The method of claim 18 wherein a Dead Sea salt mineral composition in aqueous solution is from about 5.0 to about 50.0 grams per liter of said aqueous solution.

21. The method of claim 18 wherein a Dead Sea salt mineral composition is in sterile aqueous solution.

22. The method of claim 18 wherein a Dead Sea salt mineral composition in aqueous solution contains a buffer.

23. The method of claim 22 wherein the buffer is to maintain a pH of from about 6.5 to about 7.5.

24. The method of claim 18 wherein a Dead Sea salt mineral composition in aqueous solution is about 25.0 grams per liter of said aqueous solution.

25. The method of claim 18 wherein said Dead Sea salt and mineral composition is further defined as including about 31-35% (wt/wt) magnesium halide, about 24-26% (wt/wt) potassium halide, about 4-8% (wt/wt) sodium halide, about 0.4-0.6% (wt/wt) calcium halide, the halide being about 0.3 -0.6% (wt/wt) bromide and about 99.4-99.7% (wt/wt) chloride.

26. The method of claim 18 wherein a Dead Sea salt mineral composition in aqueous solution is essentially free of noxious, organic impurities.

27. A method of producing a nasal spray formulation comprising Dead Sea salt in aqueous solution, the method comprising dissolving Dead Sea salt in aqueous solution and storing this premixed formulation in a container suitable for aerosol nasal administration.

28. The method of claim 27 wherein a Dead Sea salt mineral composition in aqueous solution is from about 0.5 to about 5 grams per liter of said aqueous solution.

29. The method of claim 27 wherein Dead Sea salt mineral composition in aqueous solution is about 25.0 grams per liter of said aqueous solution.

30. The method of claim 27 wherein Dead Sea salt mineral composition is in sterile aqueous solution.

31. The method of claim 27 wherein Dead Sea salt mineral composition in sterile aqueous solution contains a buffer.

32. The method of claim 31 wherein the buffer is to maintain a pH of from about 6.5 to about 7.5.

33. The method of claim 27 wherein said Dead Sea salt and mineral composition is further defined as including about 31-35% (wt/wt) magnesium halide, about 24-26% (wt/wt) potassium halide, about 4-8% (wt/wt) sodium halide, about 0.4-0.6% (wt/wt) calcium halide, and halide being about 0.3 -0.6% (wt/wt) bromide and about 99.4-99.7% (wt/wt) chloride.

34. The method of claim 27 wherein a Dead Sea salt mineral composition in aqueous solution is essentially free of noxious, organic impurities.

35. A nasal spray formulation comprising a Dead Sea salt and mineral composition having about 31-35% (wt/wt) magnesium halide, about 24-26% (wt/wt) potassium halide, about 4-8% (wt/wt) sodium halide, about 0.4-0.6% (wt/wt) calcium halide, the halide being about 0.3 -0.6% (wt/wt) bromide and about 99.4-99.7% (wt/wt) chloride, where said Dead Sea salt and mineral composition contains a buffer maintaining a pH from about 6.5 to 7.5 and is from about 5.0 to about 50.0 grams per liter of sterile aqueous solution and is essentially free of noxious, organic impurities.